UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
TRENTON DIVISION

WILLIAM SWINNEY and SHELLEY SWINNEY, Plaintiffs, v. JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON CO., AND MITSUBISHI TANABE PHARMA CORP. Defendants.	Civil Action No. ___________________ **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs, WILLIAM SWINNEY AND SHELLEY SWINNEY, by and through their attorneys, upon information and belief, at all times hereinafter mentioned, alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiffs as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of INVOKANA (at times referred to herein as "the subject product") for the treatment of diabetes.

2. Defendants Janssen Pharmaceuticals ("JANSSEN"), Johnson & Johnson, Co ("JOHNSON & JOHNSON"), and Mitsubishi Tanabe Pharma Corp. ("TANABE"), concealed, and continue to conceal, their knowledge of INVOKANA's unreasonably dangerous risks from Plaintiff WILLIAM SWINNEY, other consumers, and the medical community.

3. As a result of the defective nature of INVOKANA, persons who were prescribed and ingested INVOKANA, including Plaintiff WILLIAM SWINNEY, have suffered and may

continue to suffer severe and permanent personal injuries, including diabetic ketoacidosis, stroke, heart attack and severe kidney damage.

4. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff WILLIAM SWINNEY developed diabetic ketoacidosis. Plaintiff WILLIAM SWINNEY'S ingestion of the defective and unreasonably dangerous drug INVOKANA has caused and will continue to cause injury and damage to Plaintiff WILLIAM SWINNEY.

5. Plaintiff WILLIAM SWINNEY brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting INVOKANA. Plaintiff WILLIAM SWINNEY accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKANA.

PARTIES

6. Plaintiff WILLIAM SWINNEY is a citizen and resident of the State of Mississippi.

7. Plaintiff SHELLEY SWINNEY is a citizen and resident of the State of Mississippi.

8. Plaintiff WILLIAM SWINNEY began taking INVOKANA on or about February 2015 and continued to use INVOKANA until about July 2015.

9. Defendant JANSSEN is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON. JANSSEN is registered to do business in Illinois, and has designated a registered agent in Illinois. JANSSEN is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling

marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

10. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. JOHNSON & JOHNSON is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

11. Defendant TANABE is a Japanese corporation with its principal place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan. TANABE is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

JURISDICTION

12. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiffs and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

13. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a) because, at all times material hereto, Defendants JANSSEN and JOHNSON & JOHNSON had their principal place of business in this District, and all Defendants conducted substantial business in this district.

FACTUAL BACKGROUND

14. Defendant TANABE, in collaboration with Defendant JOHNSON & JOHNSON,

designed and developed the diabetes drug, INVOKANA.

15. Defendant JANSSEN, a wholly owned subsidiary of JOHNSON & JOHNSON, acquired the marketing rights to INVOKANA in North America, and marketed, advertised, distributed, and sold INVOKANA in the United States, including in the State of Mississippi.

16. INVOKANA is one of Defendants' top selling drugs, with sales of $278 million in just the first quarter of 2015.

17. In March 2013, the United States Food and Drug Administration ("FDA") approved Defendants' compound INVOKANA (*canagliflozin*) for the treatment of type 2 diabetes.

18. *Canagliflozin* is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 ("SGLT2") inhibitors, and is marketed in the United States by Defendants under the name INVOKANA.

19. SGLT2 inhibitors, including INVOKANA, primarily are used for treating type 2 diabetes. INVOKANA was the first SGLT2 inhibitor approved for use by the FDA.

20. SGLT2 inhibitors, including INVOKANA, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

21. Though INVOKANA is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continue to market INVOKANA for off label purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

22. Since INVOKANA's release, the FDA has received a significant number of

reports of diabetic ketoacidosis among users of INVOKANA.

23. An analysis of the FDA adverse event database shows that patients taking INVOKANA are several times more likely to report diabetic ketoacidosis than those taking non-SGLT2 diabetes drugs to treat diabetes.

24. Despite Defendants' knowledge of the increased risk of severe injury among INVOKANA users, Defendants did not warn patients but instead continued to defend INVOKANA, mislead physicians and the public, and minimize unfavorable findings.

25. Consumers, including Plaintiff WILLIAM SWINNEY, who have used INVOKANA for treatment of diabetes, have several alternative safer products available to treat the conditions.

26. Defendants knew of the significant risk of diabetic ketoacidosis caused by ingestion of INVOKANA. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiff WILLIAM SWINNEY, or the medical community of the severity such risks.

27. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of INVOKANA and willfully deceived Plaintiff WILLIAM SWINNEY, her health care professionals, the medical community, and the general public as to the health risks and consequences of the use of the INVOKANA.

28. As a direct result, in or about February 2014, Plaintiff WILLIAM SWINNEY was prescribed and began taking INVOKANA, primarily to treat diabetes.

29. Plaintiff WILLIAM SWINNEY ingested and used INVOKANA as prescribed and in a foreseeable manner.

30. The INVOKANA used by Plaintiff WILLIAM SWINNEY was provided to him

in a condition substantially the same as the condition in which it was manufactured and sold.

31. Plaintiff WILLIAM SWINNEY agreed to initiate treatment with INVOKANA in an effort to reduce his blood sugar. In doing so, Plaintiff WILLIAM SWINNEY relied on claims made by Defendants that INVOKANA was safe and effective for the treatment of diabetes.

32. Instead, INVOKANA can cause severe injuries, including diabetic ketoacidosis.

33. After beginning treatment with INVOKANA, and as a direct and proximate result thereof, Plaintiff WILLIAM SWINNEY suffered diabetic ketoacidosis.

34. Defendants knew or should have known the risks associated with the use of INVOKANA, including the risk of developing diabetic ketoacidosis.

35. The development of Plaintiff WILLIAM SWINNEY'S injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life- threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of INVOKANA. This conduct and the product defects complained of herein were substantial factors in bringing about and exacerbating Plaintiff WILLIAM SWINNEY'S injuries.

36. Plaintiff WILLIAM SWINNEY'S injuries were a reasonably foreseeable consequence of Defendants' conduct and INVOKANA's defects.

37. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold INVOKANA without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

38. Plaintiff WILLIAM SWINNEY would not have used INVOKANA had

Defendants properly disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated with INVOKANA, Plaintiff WILLIAM SWINNEY would have avoided the risk of developing the injuries complained of herein by not ingesting INVOKANA.

39. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff WILLIAM SWINNEY and his physicians the true and significant risks associated with taking INVOKANA.

40. As a result of Defendants' actions, Plaintiff WILLIM SWINNEY and his prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff WILLIAM SWINNEY had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

41. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff WILLIAM SWINNEY suffered severe and permanent physical and emotional injuries. Plaintiff WILLIAM SWINNEY has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff WILLIAM SWINNEY seeks actual, compensatory, and punitive damages from Defendants.

42. Plaintiff WILLIAM SWINNEY has suffered from mental anguish from the knowledge that he may suffer life-long complications as a result of the injuries caused by INVOKANA.

COUNT I
PRODUCT LIABILITY ACT — MANUFACTURING DEFECT
(N.J.S.A. 2A:58C-1, *et seq.*)

43. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

44. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling INVOKANA.

45. At all times material to this action, INVOKANA was expected to reach, and did reach, consumers in the State of Mississippi and throughout the United States, including Plaintiff WILLIAM SWINNEY, without substantial change in the condition in which it was sold.

46. At all times material to this action, INVOKANA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, INVOKANA contained manufacturing defects which rendered the subject product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;

c. The subject product was not made in accordance with Defendants' specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of Defendants.

47. The subject product manufactured and/or supplied by Defendants was not reasonably fit, suitable or safe for its intended purpose because when it left Defendants' hands, it deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae. In particular, the product is not safe, has numerous and serious side effects, and causes severe and permanent injuries including, but not limited to, developing diabetic ketoacidosis.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT II
PRODUCT LIABILITY ACT — DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-1, *et seq.*)

48. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

49. INVOKANA is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

50. At all times material to this action, INVOKANA was expected to reach, and did reach, consumers in the State of Mississippi and throughout the United States, including Plaintiff WILLIAM SWINNEY, without substantial change in the condition in which it was sold.

51. At all times material to this action, INVOKANA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, INVOKANA contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff WILLIAM SWINNEY to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing diabetic ketoacidosis and other serious injuries and side effects;

b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making the use of INVOKANA more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes ;

c. The design defects of INVOKANA existed before it left the control of Defendants;

d. INVOKANA was insufficiently and inadequately tested;

e. INVOKANA caused harmful side effects that outweighed any potential utility; and

f. INVOKANA was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff WILLIAM SWINNEY, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff WILLIAM SWINNEY.

52. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff WILLIAM SWINNEY'S injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff WILLIAM SWINNEY'S injuries without substantially impairing the product's utility.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT III
PRODUCT LIABILITY ACT — FAILURE TO WARN
(N.J.S.A. 2A:58C-1, *et seq.*)

53. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

54. INVOKANA was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff WILLIAM SWINNEY, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing diabetic ketoacidosis and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries

and side effects over other forms of treatment for type 2 diabetes. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq.*

55. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

56. Plaintiff WILLIAM SWINNEY was prescribed and used the subject product for its intended purpose.

57. Plaintiff WILLIAM SWINNEY could not have discovered any defect in the subject product through the exercise of reasonable care.

58. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

59. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

60. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

61. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, diabetic

ketoacidosis, stroke, heart attack, and severe kidney damage.

62. Plaintiff WILLIAM SWINNEY, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants

63. Defendants had a continuing duty to warn Plaintiff WILLIAM SWINNEY of the dangers associated with the subject product.

64. Had Plaintiff WILLIAM SWINNEY received adequate warnings regarding the risks of the subject product, she would not have used it.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT IV
BREACH OF EXPRESS WARRANTY

65. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

66. Defendants expressly represented to Plaintiff WILLIAM SWINNEY, other consumers, and the medical community that INVOKANA was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

67. INVOKANA does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including, but not limited to, developing diabetic ketoacidosis and other serious injuries and side effects.

68. At the time of the making of the express warranties, Defendants knew, or in the

exercise of reasonable care should have known, of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an express warranty of Defendants.

69. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

70. At all relevant times INVOKANA did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

71. Plaintiff WILLIAM SWINNEY, other consumers, and the medical community relied upon Defendants' express warranties.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT V
BREACH OF WARRANTY OF FITNESS FOR ORDINARY USE

72. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

73. Defendants warrant, as a matter of law, that the subject product is reasonably fit for its ordinary and intended use.

74. The subject product is not safe, has numerous and serious side effects and causes

severe and permanent injuries including, but not limited to, developing diabetic ketoacidosis and other serious injuries and side effects. As a result, INVOKANA is unfit and inherently dangerous for ordinary use.

75. As a direct and proximate result of Defendants' actions, Plaintiff WILLIAM SWINNEY suffered diabetic ketoacidosis. Plaintiff WILLIAM SWINNEY has and will sustain significant injuries, damages, and losses, including, but not limited to: medical and related expenses, loss of income and support, and diminished economic horizons. Plaintiff WILLIAM SWINNEY has also suffered and will continue to suffer other losses and damages, including, but not limited to: diminished capacity for the enjoyment of life, a diminished quality of life and grief.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT VI
NEGLIGENCE

76. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

77. Defendants directly or indirectly caused INVOKANA to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff WILLIAM SWINNEY.

78. The Defendants owed Plaintiff WILLIAM SWINNEY and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn

Plaintiff WILLIAM SWINNEY and other consumers of the dangers associated with INVOKANA.

79. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of INVOKANA.

80. Defendants had a duty to disclose to health care professionals the causal relationship or association of INVOKANA to the development of Plaintiff WILLIAM SWINNEY'S injuries.

81. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of INVOKANA, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of INVOKANA, including the injuries suffered by Plaintiff WILLIAM SWINNEY.

82. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold INVOKANA, Defendants knew, or in the exercise of reasonable care should have known, that their product was defective, dangerous, and otherwise harmful to Plaintiff WILLIAM SWINNEY.

83. Defendants knew, or in the exercise of reasonable care should have known, that the use of INVOKANA could cause or be associated with Plaintiff WILLIAM SWINNEY'S injuries and thus created a dangerous and unreasonable risk of injury to users of the products.

84. Defendants knew that many health care professionals were prescribing INVOKANA, and that many patients developed serious side effects including but not limited to diabetic ketoacidosis.

85. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of INVOKANA in interstate commerce, in that Defendants knew and had reason to know that a consumer's use and ingestion of INVOKANA created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff WILLIAM SWINNEY'S injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

86. Defendants were further negligent in that they manufactured and produced a defective product containing *canagliflozin*, knew and were aware of the defects inherent in the product, failed to act in a reasonably prudent manner in designing, testing, and marketing the products, and failed to provide adequate warnings of the product's defects and risks.

87. The Defendants' failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test INVOKANA before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of INVOKANA;

c. failing to conduct sufficient post-market testing and surveillance of INVOKANA;

d. designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA to consumers, including Plaintiff WILLIAM SWINNEY, without an adequate warning of the significant and dangerous risks of INVOKANA and without proper instructions to avoid foreseeable harm;

e. failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of INVOKANA and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of INVOKANA's effect on renal function;

g. failing to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment;

h. failing to exercise due care when advertising and promoting INVOKANA; and

i. negligently continuing to manufacture, market, advertise, and distribute INVOKANA after the Defendants knew or should have known of its adverse effects.

88. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff WILLIAM SWINNEY would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of INVOKANA.

89. Plaintiff WILLIAM SWINNEY did not know the nature and extent of the injuries that could result from ingestion and use of INVOKANA.

90. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff WILLIAM SWINNEY suffered, and will continue to suffer, as

described herein.

91. Defendants' conduct, as described above, was reckless. Defendants' actions and inaction risked the lives of consumers and users of their products, including Plaintiff WILLIAM SWINNEY.

92. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff WILLIAM SWINNEY suffered diabetic ketoacidosisand other related health complications. In addition, Plaintiff WILLIAM SWINNEY requires and will continue to require healthcare and services. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur medical and related expenses. Plaintiff WILLIAM SWINNEY also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff WILLIAM SWINNEY'S direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT VII
BREACH OF IMPLIED WARRANTY

93. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

94. Defendants manufactured, distributed, advertised, promoted, and sold

INVOKANA.

95. At all relevant times, Defendants knew of the use for which INVOKANA was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

96. Defendants were aware that consumers, including Plaintiff WILLIAM SWINNEY, would use INVOKANA for treatment of type 2 diabetes and for other purposes, including but not limited to weight loss, and reduced blood pressure.

97. INVOKANA was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that INVOKANA has dangerous propensities when used as intended and can cause serious injuries, including diabetic ketoacidosis, stroke, heart attack, and severe kidney damage..

98. At all relevant times, Defendants intended that INVOKANA be used in the manner used by Plaintiff WILLIAM SWINNEY, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such use, despite the fact that INVOKANA was not adequately tested.

99. Defendants were aware that consumers, including Plaintiff WILLIAM SWINNEY, would use INVOKANA as marketed by Defendants. As such, Plaintiff WILLIAM SWINNEY was a foreseeable user of INVOKANA.

100. Upon information and belief, Plaintiff WILLIAM SWINNEY and/or his health care professionals were at all relevant times in privity with Defendants.

101. INVOKANA was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff WILLIAM SWINNEY'S injuries.

102. Plaintiff WILLIAM SWINNEY and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell INVOKANA only if it was indeed of merchantable quality and safe and fit for its intended use.

103. Defendants breached their implied warranty to consumers, including Plaintiff WILLIAM SWINNEY. INVOKANA was not of merchantable quality, nor was it safe and fit for its intended use.

104. Plaintiff WILLIAM SWINNEY and his physicians reasonably relied upon Defendants' implied warranty for INVOKANA when prescribing and ingesting INVOKANA.

105. Plaintiff WILLIAM SWINNEY'S use of INVOKANA was as prescribed and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

106. INVOKANA was expected to reach and did in fact reach consumers, including Plaintiff WILLIAM SWINNEY, without substantial change in the condition in which it was manufactured and sold by Defendants.

107. Defendants breached the warranties of merchantability and fitness for its particular purpose because INVOKANA was unduly dangerous and caused undue injuries, including Plaintiff WILLIAM SWINNEY'S injuries.

108. The harm caused by INVOKANA far outweighed its alleged benefit, rendering INVOKANA more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

109. Neither Plaintiff WILLIAM SWINNEY nor his health care professionals reasonably could have discovered or known of the risk of serious injury and death associated with INVOKANA.

110. Defendants' breach of these implied warranties caused Plaintiff WILLIAM

SWINNEY'S injuries.

111. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff WILLIAM SWINNEY suffered, diabetic ketoacidosis and other related health complications. In addition, Plaintiff WILLIAM SWINNEY requires and will continue to require healthcare and services. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur medical and related expenses. Plaintiff WILLIAM SWINNEY also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff WILLIAM SWINNEY'S direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff WILLIAM SWINNEYhas incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT VIII
FRAUDULENT MISREPRESENTATION

112. Plaintiff WILLIAM SWINNEY restates the allegations set forth above as if fully rewritten herein.

113. Defendants made fraudulent misrepresentations with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes; and

b. Upon information and belief, Defendants represented that INVOKANA was safer than other alternative medications.

114. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of INVOKANA to Plaintiff WILLIAM SWINNEY, other consumers, Plaintiff WILLIAM SWINNEY'S physicians, and the medical community.

115. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff WILLIAM SWINNEY and his physicians, rely upon them.

116. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff WILLIAM SWINNEY, other consumers, Plaintiff WILLIAM SWINNEY'S physicians, and the medical community to induce and encourage the sale of INVOKANA.

117. Plaintiff WILLIAM SWINNEY, his doctors, and others relied upon these representations.

118. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff WILLIAM SWINNEY suffered, diabetic ketoacidosis and other related health complications. In addition, Plaintiff WILLIAM SWINNEY requires and will continue to require healthcare and services. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur medical and related expenses. Plaintiff WILLIAM SWINNEY also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting

conditions, activation of latent conditions, and other losses and damages. Plaintiff WILLIAM SWINNEY'S direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT IX
NEGLIGENT MISREPRESENTATION

119. Plaintiff WILLIAM SWINNEY restates the allegations set forth above as if fully rewritten herein.

120. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning INVOKANA, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

121. Defendants disseminated to health care professionals and consumers — through published labels, marketing materials, and otherwise — information that misrepresented the properties and effects of INVOKANA with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest INVOKANA.

122. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals and consumers of INVOKANA rely on information disseminated and marketed to

them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting INVOKANA.

123. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of INVOKANA were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff WILLIAM SWINNEY.

124. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals would write prescriptions for INVOKANA in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for INVOKANA would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

125. From the time INVOKANA was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of INVOKANA. Defendants made material misrepresentations to Plaintiff WILLIAM SWINNEY, his health care professionals, the healthcare community, and the general public, including:

a. stating that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes;

b. concealing, misrepresenting, and actively downplaying the severe and life-threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative drug therapies; and

c. misrepresenting INVOKANA's risk of unreasonable, dangerous, adverse side effects.

126. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

127. These representations were made directly by Defendants, their sales representative, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

128. Defendants made these representations with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of INVOKANA.

129. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff WILLIAM SWINNEY, the truth regarding Defendants' claims that INVOKANA had been tested and found to be safe and effective for treating diabetes.

130. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

131. Defendants failed to exercise ordinary care in making their representations concerning INVOKANA and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of INVOKANA.

132. Defendants engaged in a nationwide marketing campaign, over-promoting INVOKANA in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of

INVOKANA while concealing, misrepresenting, and actively downplaying the serious, severe, and life- threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented INVOKANA's risk of unreasonable and dangerous adverse side effects.

133. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff WILLIAM SWINNEY. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

134. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff WILLIAM SWINNEY suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff WILLIAM SWINNEY requires and will continue to require healthcare and services. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur medical and related expenses. Plaintiff WILLIAM SWINNEY also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff WILLIAM SWINNEY direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT X
FRAUDULENT CONCEALMENT

135. Plaintiff WILLIAM SWINNEY restates the allegations set forth above as if fully rewritten herein.

136. Throughout the relevant time period, Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of INVOKANA.

137. Defendants fraudulently concealed information with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKANA was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using INVOKANA; and

b. Upon information and belief, Defendants represented that INVOKANA was safer than other alternative medications and fraudulently concealed information which demonstrated that INVOKANA was not safer than alternatives available on the market.

138. Defendants were under a duty to Plaintiff WILLIAM SWINNEY to disclose

and warn of the defective and dangerous nature of INVOKANA because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of INVOKANA;

b. Defendants knowingly made false claims and omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of INVOKANA from Plaintiff WILLIAM SWINNEY.

139. As the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, Defendants had unique knowledge and special expertise regarding INVOKANA. This placed them in a position of superiority and influence over Plaintiff WILLIAM SWINNEY and his healthcare providers. As such, Plaintiff WILLIAM SWINNEY and his healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

140. The facts concealed or not disclosed by Defendants to Plaintiff WILLIAM SWINNEY were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use INVOKANA.

141. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by INVOKANA was intentional, and the representations made by Defendants were known by them to be false.

142. The concealment of information and the misrepresentations about

INVOKANA were made by Defendants with the intent that doctors and patients, including Plaintiff WILLIAM SWINNEY, rely upon them so that Plaintiff WILLIAM SWINNEY would request and purchase INVOKANA and his health care providers would prescribe and recommend INVOKANA.

143. Plaintiff WILLIAM SWINNEY, his doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by INVOKANA.

144. Had Defendants not concealed or suppressed information regarding the severity of the risks of INVOKANA, Plaintiff WILLIAM SWINNEY and his physicians would not have prescribed or ingested the drug.

145. Defendants, by concealment or other action, intentionally prevented Plaintiff WILLIAM SWINNEY and his health care professionals from acquiring material information regarding the lack of safety of INVOKANA, thereby preventing Plaintiff WILLIAM SWINNEY from discovering the truth. As such, Defendants are liable for fraudulent concealment.

146. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff WILLIAM SWINNEY suffered, diabetic ketoacidosis and other related health complications. In addition, Plaintiff WILLIAM SWINNEY requires and will continue to require healthcare and services. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur medical and related expenses. Plaintiff WILLIAM SWINNEY also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff WILLIAM SWINNEY'S direct medical losses and costs include

physician care, monitoring, and treatment. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT XI
FRAUD

147. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

148. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff WILLIAM SWINNEY, his prescribing health care professionals, the health care industry, and consumers that INVOKANA had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment.

149. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risk of adverse health events associated with use of INVOKANA. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of INVOKANA, such as Plaintiff WILLIAM SWINNEY.

150. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff WILLIAM SWINNEY and his prescribing health care professionals, so as to induce them to

recommend, prescribe, dispense, or purchase INVOKANA, despite the risk of severe life threatening injury, which Defendants knew were caused by the products.

151. Defendants fraudulently and intentionally concealed material information, as aforesaid. Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risks.

152. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, which were known by Defendants to result from use of INVOKANA.

153. Defendants fraudulently and intentionally suppressed information about the severity of the risks and injuries associated with INVOKANA from physicians and patients, including Plaintiff WILLIAM SWINNEY and his prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of the INVOKANA. For example:

a. INVOKANA was not as safe and effective as other diabetes drugs given its intended use;

b. Ingestion of INVOKANA does not result in a safe and more effective method of diabetes treatment than other available treatments;

c. The risks of harm associated with the use of the INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies;

d. The risk of adverse events with INVOKANA was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. Defendants knew that the risks of harm associated with the use of INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff WILLIAM SWINNEY relied when ingesting INVOKANA;

f. The limited clinical testing revealed that INVOKANA had an unreasonably high risk of injury, including Plaintiff WILLIAM SWINNEY'S injuries, above and beyond those associated with other diabetes drug therapies;

g. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

h. Defendants had knowledge of the dangers involved with the use of INVOKANA, which dangers were greater than those associated with other diabetes drug therapies;

i. Defendants intentionally and knowingly failed to disclose that patients using INVOKANA could suffer diabetic ketoacidosis and sequelae, and would require monitoring while treating with INVOKANA drug therapy; and/or

j. INVOKANA was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

154. Defendants had access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest INVOKANA, information that was not publicly disseminated or made available, but instead was actively suppressed by the Defendants.

155. Defendants' intentional concealment and omissions of material fact concerning the safety of INVOKANA was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Plaintiff WILLIAM SWINNEY, and with reckless intent to mislead, so as to cause Plaintiff WILLIAM SWINNEY'S prescribing health care professionals to purchase, prescribe, and/or dispense INVOKANA, and to cause Plaintiff WILLIAM SWINNEY to rely on Defendants' fraudulent misrepresentations that INVOKANA was a safe and effective diabetes drug therapy.

156. At the time Plaintiff WILLIAM SWINNEY purchased and used INVOKANA, Plaintiff WILLIAM SWINNEY was unaware that Defendants had made misrepresentations and omissions, and instead Plaintiff WILLIAM SWINNEY reasonably believed Defendants' representations to constitute true, complete, and accurate portrayal of INVOKANA's safety and efficacy.

157. Defendants knew and had reason to know that INVOKANA could and would cause serious personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

158. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff WILLIAM SWINNEY was induced to use and in fact used INVOKANA, thereby sustaining injuries and damages. Defendants knew and had reason to know that Plaintiff WILLIAM

SWINNEY and his health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff WILLIAM SWINNEY and his health care professionals would not have prescribed and ingested INVOKANA if the true facts regarding the drug had not been concealed by Defendants.

159. During the marketing and promotion of INVOKANA to health care professionals, neither Defendants nor the co-promoters who were detailing INVOKANA on Defendants' behalf, warned health care professionals, including Plaintiff WILLIAM SWINNEY prescribing health care professionals, that INVOKANA caused or increased the risk of harm of diabetic ketoacidosis.

160. Plaintiff WILLIAM SWINNEY reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of INVOKANA.

161. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Plaintiff WILLIAM SWINNEY, the public, Plaintiff WILLIAM SWINNEY'S health care professionals, and the health care industry that INVOKANA was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

162. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff WILLIAM SWINNEY. Defendants knew of INVOKANA's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

163. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff WILLIAM SWINNEY suffered, diabetic

ketoacidosis and other related health complications. In addition, Plaintiff WILLIAM SWINNEY requires and will continue to require healthcare and services. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur medical and related expenses. Plaintiff WILLIAM SWINNEY also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff WILLIAM SWINNEY'S direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff WILLIAM SWINNEY has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT XII
PUNITIVE DAMAGES ALLEGATIONS

164. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

165. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff WILLIAM SWINNEY, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff WILLIAM SWINNEY. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to

or a conscious disregard for to the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff WILLIAM SWINNEY and his healthcare providers.

166. Plaintiff WILLIAM SWINNEY relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

167. Plaintiff WILLIAM SWINNEY therefore asserts claims for exemplary damages.

168. Plaintiff WILLIAM SWINNEY also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff WILLIAM SWINNEY.

169. Plaintiff WILLIAM SWINNEY is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff WILLIAM SWINNEY, by making intentionally false and fraudulent misrepresentations about the safety of INVOKANA. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of INVOKANA, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting INVOKANA, despite their knowledge and awareness of these serious side effects and risks.

170. Defendants had knowledge of, and were in possession of evidence demonstrating that INVOKANA caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading information with

regard to the product's safety to regulatory agencies, the medical community, and consumers of INVOKANA.

171. Although Defendants knew or recklessly disregarded the fact that INVOKANA causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute INVOKANA to consumers, including Plaintiff WILLIAM SWINNEY, without disclosing these side effects when there were safer alternative methods for treating diabetes.

172. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing INVOKANA and consumers from purchasing and ingesting INVOKANA, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming INVOKANA.

173. Defendants knew of INVOKANA's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff WILLIAM SWINNEY, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by INVOKANA.

174. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff WILLIAM SWINNEY and other INVOKANA users and for the primary purpose of increasing Defendants' profits from the sale and distribution of INVOKANA. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

175. Prior to the manufacture, sale, and distribution of INVOKANA, Defendants knew

that the drug was in a defective condition and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff WILLIAM SWINNEY. As such, Defendants unreasonably subjected consumers of INVOKANA to risk of injury or death.

176. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in INVOKANA and failed to adequately warn the public, including Plaintiff WILLIAM SWINNEY, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of INVOKANA knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

177. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff WILLIAM SWINNEY, entitling Plaintiff WILLIAM SWINNEY to exemplary damages.

WHEREFORE, Plaintiff WILLIAM SWINNEY respectfully requests that this Court enter judgment in Plaintiff WILLIAM SWINNEY'S favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff WILLIAM SWINNEY also demands that the issues contained herein be tried by a jury.

COUNT XIII
LOSS OF CONSORTIUM

178. Plaintiff restates the allegations set forth above as if fully rewritten herein.

179. At all relevant times stated herein, Plaintiff SHELLEY SWINNEY was and is the husband and spouse of Plaintiff WILLIAM SWINNEY.

180. As a result of the injuries sustained by Plaintiff WILLIAM SWINNEY, as set forth above, Plaintiff SHELLEY SWINNEY has suffered loss of consortium, including but not limited to, mental anguish and the loss of his wife's support, services, society, companionship, comfort, affection, love, and solace.

181. As a result of the injuries sustained by Plaintiff WILLIAM SWINNEY, as set forth above, Plaintiffs WILLIAM SWINNEY and SHELLEY SWINNEY sustained damage to their marital relationship.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against each of the Defendants, and each of them individually, jointly, and severally, as follows:

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Pain and suffering;

4. Loss of consortium;

5. Non-economic damages for an increased risk of future complications as a direct result of plaintiff WILLIAM SWINNEY'Sinjury;

6. Punitive damages;

7. Prejudgment interest at the highest lawful rate allowed by law;

8. Interest on the judgment at the highest legal rate from the date of judgment until collected;

9. Attorneys' fees, expenses, and costs of this action; and

10. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all issues so triable.

Respectfully submitted,

SEEGER WEISS LLP

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Attorneys for Plaintiffs

Dated: April 5, 2016